WISCONSIN LEGISLATIVE COUNCIL
REPORT TO THE LEGISLATURE

Legislation Recommended by the Special Committee on Use of Prescription Drugs for Children

- 2001 Assembly Bill 672, Relating to Requiring Physicians to Provide Certain Information When Issuing Prescription Orders to Treat Children With Attention Deficit Hyperactivity Disorder

December 10, 2001

RL 2001-10

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LEGISLATION RECOMMENDED BY THE SPECIAL COMMITTEE ON USE OF PRESCRIPTION DRUGS FOR CHILDREN

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December 10, 2001

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PART I

KEY PROVISIONS OF LEGISLATION

- 2001 Assembly Bill 672, relating to requiring physicians to provide certain information when issuing prescription orders to treat children with attention deficit hyperactivity disorder.

A. Requirement for Physicians to Provide Information When Prescribing a Drug to Treat Attention Deficit Hyperactivity Disorder

- Requires a physician who diagnoses a child with attention deficit hyperactivity disorder (ADHD) and prescribes medication for its treatment to provide certain information about the assessment and treatment of ADHD to the parent or guardian of the child or to an adult who is with the child. If the child is 14 years of age or older, the physician must also provide the information to the child.

- Requires a physician who prescribes a Schedule II controlled substance for treatment of ADHD in a child to provide certain information about the prescribed substance to the parent or guardian of the child or to an adult who is with the child. If the child is 14 years of age or older, the physician must also provide the information to the child.

B. Requirement for Department of Health and Family Services to Prepare Informational Materials

- Requires the Department of Health and Family Services (DHFS) to prepare informational materials about the assessment and treatment of ADHD and make these materials available to physicians and the public on its Web site.

- Requires DHFS to prepare informational materials about Schedule II controlled substances that are routinely prescribed by physicians in this state to treat ADHD in children. These materials must also be made available to physicians and the public on DHFS's Web site.

C. Dissemination of Materials by Department of Public Instruction

- Requires the Department of Public Instruction (DPI) to disseminate the materials prepared by DHFS, described in B., above, to appropriate public school staff.

PART II

COMMITTEE ACTIVITY

A. ASSIGNMENT

The Joint Legislative Council established the Special Committee and appointed the Co-Chairs by a June 13, 2000 mail ballot and members by an October 12, 2000 mail ballot. The Special Committee was directed to study issues surrounding the use of prescription drugs to modify children's behavior, including the safety, efficacy and appropriateness of the use of those drugs and determine whether such drugs are safely and appropriately prescribed and labeled.

Membership of the Special Committee consisted of one Senator, five Representatives and 14 Public Members. A list of the committee membership is set forth in **Appendix 3**.

B. SUMMARY OF MEETINGS

The committee held six meetings at the State Capitol in Madison on the following dates:

November 16, 2000	March 2, 2001
December 19, 2000	April 17, 2001
January 23, 2001	May 22, 2001

At the November 16, 2000 meeting, the committee heard testimony from Dr. Hugh Johnston, a Professor at the University of Wisconsin (UW)-Madison, on the use of psychotropic drugs and the diagnosis of ADHD. The committee members had an opportunity to question Dr. Johnston on a wide range of issues related to the general assignment of the committee. The committee also heard testimony from Cindy Benning, who is the Chair of the State Controlled Substances Board and a member of the Pharmacy Examining Board. She provided information on the various regulations relating to the dispensing and monitoring of drugs, such as Ritalin, used to treat ADHD. Ms. Benning also provided testimony on a proposal to monitor drug usage in the state.

At the December 19, 2000 meeting, the committee heard testimony from Colonel Dr. Roger Lalich, State Surgeon, who reviewed military recruiting policies for the committee. He noted that potential recruits who are using certain drugs such as Ritalin are not eligible for military service. He noted that recruits who have been diagnosed with ADHD in the past may be eligible to serve only if they are approved through a waiver procedure.

Stefanie Petska, Director, Special Education, DPI, discussed the applicable special education laws and procedures with the committee. She also discussed issues relating to effectively dealing with the educational needs of children with ADHD.

Professor William Frankenberger, of the UW-Eau Claire, gave an extensive presentation on his research relating to ADHD and Ritalin use. Professor Frankenberger

provided data relating to the substantial increase in use of Ritalin in the last decade and on his unique long-term studies of educational performance by students taking Ritalin. Professor Frankenberger's presentation elicited numerous questions from the committee.

At the January 23, 2001 meeting, the committee viewed a videotape produced by Fred A. Baughman, M.D., and held a discussion with him by teleconference. Dr. Baughman is an outspoken critic of the use of Ritalin and other similar drugs by children and he disputes the existence of ADHD. The committee next heard from Brenda Krupa, the President of the Wisconsin Association of School Nurses (WASN) and Jan Blume, WASN Secretary. They described the role of school nurses in addressing behavioral problems identified by teachers, the procedures followed when medications are dispensed in the schools, and the numbers of students taking medications to treat ADHD. The committee then discussed some of the information which had been presented and requested further information regarding several topics.

At the March 2, 2001 meeting, the committee heard its second presentation from Professor William Frankenburger of the UW-Eau Claire. He discussed research on ADHD conducted by the Human Development Center, which examined issues such as rates of stimulant usage among various populations, effect of usage on academic achievement and side effects of stimulant usage. He also discussed other explanations for ADHD-type behavior such as learning difficulties or emotional problems and ways to address those problems other than through medication. Committee discussion revolved around the issue of informing parents about various aspects of stimulant use to treat ADHD, and staff was directed to prepare a bill draft that would require parents to be provided with certain information at the time their child is prescribed a stimulant to treat ADHD.

At the April 19, 2001 meeting, the committee discussed a variety of issues that could be considered for legislation. The committee also discussed WLC: 0101/1, draft legislation that had been distributed to the committee prior to the meeting. That bill would require parents to be provided with certain information at the time their child is prescribed a stimulant to treat ADHD. During the committee discussion, members expressed their opinions regarding the provisions of the proposed legislation.

At the conclusion of the meeting, the committee directed staff to prepare a revised draft taking into account the concerns expressed by the committee members. It was also decided that the Co-Chairs of the committee should meet with DHFS to discuss the proposed activities for that department that are contained in the draft legislation.

At the May 22, 2001 meeting, the committee reviewed the second version of WLC: 0101/2, the draft legislation which the committee developed. The draft requires DHFS to prepare informational materials about certain Schedule II controlled substances and ADHD and requires a physician to provide these materials to the parent of a child for whom they prescribe a Schedule II substance to treat ADHD. The draft also requires a physician to provide the parents with a detailed explanation of the method they used to diagnose ADHD in their child. The committee, after its review, requested several modifications to the draft. Committee Co-Chairs Grothman and Breske directed staff to modify the draft to reflect the

concerns expressed by committee members. The Co-Chairs stated that the revised draft would be sent to committee members and voted upon by a mail ballot.

PART III

RECOMMENDATION

This part of the report provides background information on, and a description of, the legislation recommended by the Special Committee on Use of Prescription Drugs for Children, and approved by the Joint Legislative Council.

2001 ASSEMBLY BILL 672

A. BACKGROUND

Attention deficit hyperactivity disorder is the most commonly diagnosed neurobehavioral disorder in American children. According to the National Institute of Mental Health (NIMH), ADHD is a chronic neurobiological disorder that interferes with an individual's capacity to regulate activity level, inhibit behavior and attend to tasks in developmentally appropriate ways. It is estimated that between 3% and 5% of school-age children in the United States have ADHD.[1]

The most common medications used to treat ADHD are psychostimulant medications, including methylphenidate, most often in the form of Ritalin, and amphetamines such as Dexedrine and Adderall. According to statistics gathered by the Drug Enforcement Administration, the quantity of stimulants manufactured to treat ADHD and other ailments in the United States rose dramatically in the 1990s. Production of amphetamines, including Adderall and Dexedrine, rose more than 20-fold. Production of methylphenidate, marketed as Ritalin and other drugs, rose eight-fold.

During the past decade, the number of American children receiving medication based on the diagnosis of ADHD has increased greatly. From 1995 to 2000, the number of prescriptions written for Ritalin in the United States increased from 4.5 million to 11.4 million, according to IMS Health, an international health care information organization. A report in the Journal of the American Medical Association (JAMA) indicates that the rate of prescribing psychotropic medications for preschool children rose three-fold between 1991 and 1995.[2]

Concern has been raised that the use of stimulant medications to treat ADHD may have unintended effects on children's development and may pose other health risks. The methylphenidate drugs, such as Ritalin, are classified as Schedule II drugs under the Federal Controlled Substances Act and in the state under s. 961.16, Stats. Classification as a Schedule II substance by the State Controlled Substances Board must be based upon findings that:

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[1] NIMH, ADHD--Questions and Answers.

[2] JAMA, *Trends in the Prescribing of Psychotropic Medications to Preschoolers*, February 23, 2000.

1. The substance has "high potential for abuse;

2. The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

3. The abuse of the substance may lead to severe psychological or physical dependence.

Recently, articles have appeared in several medical journals examining whether ADHD is being over diagnosed. Some critics question whether ADHD really exists, since there is no independent diagnostic test for ADHD, such as a blood test or brain scan. The National Institute of Health (NIH) considered this argument during its Consensus Development Conference on ADHD in November 1998, and concluded that although an independent diagnostic test does not exist, there is evidence supporting the validity of ADHD. The NIH stated that although research has suggested a central nervous system basis for ADHD, further research is necessary to firmly establish ADHD as a brain disorder. The NIH pointed out that this is the case for most psychiatric disorders.

Committee members heard testimony that children diagnosed with ADHD may, in fact, be exhibiting ADHD-like behavior for other reasons, such as vision or hearing problems, learning disorders or problems related to lead poisoning. Committee members were also told that the diagnosis of ADHD can be complex and that some practitioners may not be adequately assessing children before concluding that a child has ADHD. Testimony was also received indicating that interventions other than a medication can sometimes be effective in improving ADHD-like behavior. These include psychotherapy, behavior modification, use of behavioral techniques in the school setting, parent training, modification of educational curricula, better student-to-teacher ratios or other environmental accommodations, such as the development of a highly structured environment. However, since these interventions may be more time consuming and expensive than medications, it is feared that they may not be utilized to their full potential.

Committee members also heard testimony that sometimes school personnel will encourage or even pressure parents to have their child prescribed Ritalin or other medication if the child misbehaves in the classroom. Some committee members expressed concern that because of these pressures and the fact that the diagnosis of ADHD and the use of stimulant medications to treat ADHD have become relatively commonplace, parents may not be aware of, or fully consider the possibility of misdiagnosis, the potential risks of medication or the fact that other treatments may be available.

Seven other states have enacted legislation related to the diagnosis and treatment of ADHD. For example, California required the establishment of standards for the administration of psychotropic medications to any person under state jurisdiction; Maryland established a council on ADHD to review the literature and research on ADHD, provide educational programs and materials regarding ADHD to the public and to assist school districts in designing and implementing written guidelines for the optimal diagnosis and treatment of ADHD; Washington required collection of data on the number of children in foster care receiving psychotropic medications to address behavioral problems; and Rhode

Island requested pediatric health care practitioners to develop a brochure to inform parents about potential side effects of psychotropic drugs prescribed for children. In addition, the Colorado State Board of Education passed a resolution that, among other things, encourages school personnel to use classroom management solutions to resolve behavioral difficulties.

Doctors currently must obtain "informed consent" of any patient before providing them treatment or prescribing a drug for them. There is no general statutory requirement governing informed consent, although there are several statutory and administrative rule provisions relating to informed consent in specific circumstances. However, there is no current statutory requirement for disclosures related to a specific drug or class of drugs as proposed in WLC: 0101/3. The bill is not intended to replace any requirement for obtaining the informed consent of the patient currently in place.

B. DESCRIPTION OF THE BILL

Requirements for Physicians

Information to be Provided When Prescribing Medication for ADHD in a Child

2001 Assembly Bill 672 requires any physician who diagnoses a child (any person less than 18 years old) with ADHD and prescribes medication for treatment of the disorder to provide information on the assessment and treatment of ADHD. The information must be provided to the parent or guardian of the child if they are with the child when the prescription order is issued. If the parent or guardian is not with the child, the physician must provide the information to an adult who is with the child at the time the prescription order is issued, if any. If the child is 14 years of age or older, the physician must also provide the information to the child.

Under the circumstances described above, a physician must provide all of the following information:

1. An explanation of the method of diagnosis used, including the results of any tests or evaluations.

2. Information on alternative modes of treatment, as provided in s. 448.30, Stats., which provides as follows:

> **448.30 Information on alternate modes of treatment.** Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician's duty to inform the patient under this section does not require disclosure of:
>
> **(1)** Information beyond what a reasonably well-qualified physician in a similar medical classification would know.

(2) Detailed technical information that in all probability a patient would not understand.

(3) Risks apparent or known to the patient.

(4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.

(5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.

(6) Information in cases where the patient is incapable of consenting.

3. A printed copy of the informational materials pertaining to the assessment and treatment of ADHD prepared by DHFS. A description of those materials, along with the requirement for DHFS to prepare the materials, is set forth below.

If a physician treats a child for ADHD with a prescription drug on a long-term basis, the physician must provide all of the information described above when issuing the initial prescription order and at least once every two years thereafter. A physician is not required to provide the information in an emergency or if the physician reasonably believes that another physician has issued a prescription order for the child for the same prescription drug within the past year.

Information to be Provided When Prescribing a Schedule II Controlled Substance for Treatment of ADHD in a Child

In addition to the materials described above, the bill requires a physician who prescribes a Schedule II controlled substance for treatment of ADHD in a child to provide a printed copy of any materials pertaining to the substance which have been prepared by DHFS. The requirement for DHFS to prepare those materials is set forth below.

Written Certification

A physician who is required to provide any of the information described above must obtain certification in writing from the parent or guardian of the child, or the adult to whom the information is provided, if any, that the physician has provided all of the required information.

Penalty for Failure to Provide Information; Exemption

Under current law, a physician who, after investigation and a hearing, is found guilty of unprofessional conduct is subject to disciplinary action by the medical examining board. The bill provides that an allegation that a physician has failed to provide the required information or obtain the required certification, described above, is an allegation of unprofessional conduct. However, the bill provides that it is not unprofessional conduct for a physician to fail to provide the informational materials prepared by DHFS, if the physician

made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make materials available at the time the physician was required to provide them.

Preparation of Informational Materials by DHFS

Materials Pertaining to the Assessment and Treatment of ADHD

The bill requires DHFS to prepare informational materials on the assessment and treatment of ADHD. These are the materials which must be provided by a physician who prescribes any prescription drug for the treatment of ADHD in a child. The materials must contain the following:

1. A summary of the practice parameters for the assessment and treatment of children and adolescents with ADHD published by the American Academy of Child and Adolescent Psychiatry.

2. A statement that a parent or guardian may seek treatment other than prescription drugs for a child with ADHD.

Materials Pertaining to Schedule II Controlled Substances

In addition to the materials above, the bill requires DHFS to prepare informational materials on certain Schedule II controlled substances. These are the additional materials that must be provided by a physician who prescribes any Schedule II controlled substance for treatment of ADHD in a child. DHFS must, in consultation with the State Medical Society of Wisconsin, determine which Schedule II controlled substances are routinely prescribed by physicians in this state to treat ADHD in children. For each of these substances, DHFS must prepare materials containing the following information:

1. A statement that the substance is a Schedule II controlled substance under s. 961.16.

2. A summary of information included in the labeling of the substance required by federal law pertaining to the safety and effectiveness of the substance when used to treat ADHD in children, including any information relating to the potential for abuse or development of dependence upon the drug.

3. A statement that use of a the Schedule II controlled substance to treat ADHD may affect a person's eligibility to serve in the U.S. Armed Forces, if the department so finds.

4. A statement that the use of a Schedule II controlled substance to treat ADHD may affect the cost of a person's health insurance.

DHFS must prepare all of the informational materials within approximately five months after the effective date of the bill. Physicians are first required to provide the required information beginning approximately nine months after the effective date of the bill.

Dissemination of Materials by DPI

The bill requires DPI to disseminate the informational materials prepared by DHFS to appropriate public school staff.

APPENDIX 1

Committee and Joint Legislative Council Votes

By a mail ballot, the Special Committee voted to recommend WLC: 0101/3 for introduction in the 2001-02 Session of the Legislature. The vote was as follows:

- WLC: 0101/3, relating to information provided by a physician when certain substances are prescribed for children: Ayes, 17 (Reps. Grothman, Underheim, Wasserman and Williams; Sen. Breske; and Public Members Augustine, Dean, Goeden, Hayes, Koenings-Heigl, Larson, Paulson, Balestreri-Roden, Bradshaw-Rouse, Schaal, Seefeldt and Ward); Noes, 3 (Rep. McCormick; and Public Members Chou and Friedman).

At its meeting on June 27, 2001, the Joint Legislative Council voted to introduce WLC: 0103/3 in the 2001-02 Session of the Legislature. The vote on the draft was as follows:

- WLC: 0101/3, relating to information provided by a physician when certain substances are prescribed for children: Ayes, 16 (Sens. Risser, Baumgart, Burke, Chvala, George, Grobschmidt and Robson; and Reps. Rhoades, Black, Foti, Freese, Huber, Jensen, Lehman, Meyerhofer and Stone; Noes, 2 (Sens. Darling and Rosenzweig); and Absent, 4 (Sens. Panzer and Zien; and Reps. Bock and Gard).

APPENDIX 2

JOINT LEGISLATIVE COUNCIL
s. 13.81, Stats.

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This 22-member committee consists of the majority and minority party leadership of both houses of the Legislature, the cochairs and ranking minority members of the Joint Committee on Finance, and 5 Senators and 5 Representatives appointed as are members of standing committees.

APPENDIX 3

USE OF PRESCRIPTION DRUGS FOR CHILDREN, SPECIAL COMMITTEE ON

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STUDY ASSIGNMENT: The Committee shall study issues surrounding the use of prescription drugs to modify children's behavior, including the safety, efficacy and appropriateness of the use of those drugs and determine whether such drugs are safely and appropriately prescribed and labeled. The Special Committee shall report its recommendations to the Joint Legislative Council by January 1, 2001.

Established and Cochairs appointed by a June 13, 2000 mail ballot; members appointed by an October 12, 2000 mail ballot.

20 MEMBERS: 1 Senator; 5 Representatives and 14 Public Members.

LEGISLATIVE COUNCIL STAFF: Mary Matthias, Senior Staff Attorney; Russ Whitesel, Senior Staff Attorney; and Kelly Mautz, Support Staff.

(1) Formerly a Public Member of the Special Committee; became a member of the 2001 Wisconsin Assembly on January 3, 2001.

APPENDIX 4

Committee Materials List

November 16, 2000 Meeting

Rethinking Ritalin, ***The CQ Researcher***, Congressional Quarterly Inc., Vol. 9, No. 40, pp. 905-928 (10-22-99) (provided only to committee members)

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Psychotropic Medication and Children, ***NCSL LegisBrief*****,** National Conference of State Legislatures, Vol. 8, No. 40 (10-00) (provided only to committee members)

Article, Ritalin, , National Institute on Drug Abuse, National Institutes of Health

Article, Lawmakers express concern about increased use of Ritalin, ***Stateline Midwest***, Council of State Governments (8-00)

Publication, Attention Deficit Hyperactivity Disorder (ADHD) – Questions and Answers, National Institute of Mental Health

Publication, Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder, Consensus Statements, NIH Consensus Development Program, National Institutes of Health

December 19, 2000 Meeting

Package insert for **Ritalin**

Presentation by **Professor William Frankenberger**, Associate Professor, University of Wisconsin-Eau Claire

January 23, 2001 Meeting

Memo No. 1, Administration of Drugs to Pupils and Emergency Care (1-11-01)

Standards of Medical Fitness, Army Regulation 40-501, distributed at the request of Colonel Roger Lalich, State Surgeon

March 2, 2001 Meeting

Memo No. 2, Legislation in Other States Regarding the Use of Psychotropic Drugs for Children (2-21-01)

Article, "Clinical Practice Guideline: Diagnosis and Evaluation of the Child With Attention-Deficit/Hyperactivity Disorder," American Academy of Pediatrics, Vol. 105, No. 5 (5-00)

April 17, 2001 Meeting

WLC: 0101/1, relating to information provided by a physician when certain substances are prescribed for children

May 22, 2001 Meeting

WLC: 0101/2, relating to information provided by a physician when certain substances are prescribed for children